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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/651,992	09/02/2003	John E. Hutchins	BSX-214.1CON	1427	
7590 07/26/2006			EXAM	INER	
Steven M. War Fulbright & Jaworski L.L.P. 801 Pennsylvania Avenue, N.W. Washington, DC 20004-2623			WOO, JULIAN W		
			ART UNIT	PAPER NUMBER	
			3731		
			DATE MAILED: 07/26/2006	DATE MAILED: 07/26/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/651,992	HUTCHINS ET AL.			
Office Action Summary	Examiner	Art Unit			
	Julian W. Woo	3731			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period variety or Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI	lely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on 09 M	ay 2005.				
2a) This action is <b>FINAL</b> . 2b) ⊠ This	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	33 O.G. 213.			
Disposition of Claims					
4)  Claim(s) 7,8,10-12 and 15-19 is/are pending in 4a) Of the above claim(s) is/are withdray 5)  Claim(s) is/are allowed.  6)  Claim(s) 7,8,10-12 and 15-19 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/o	wn from consideration.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority documents application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Application rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)  1) Motice of References Cited (PTO-892)  2) Dotice of Draftsperson's Patent Drawing Review (PTO-948)	4) ☐ Interview Summary Paper No(s)/Mail Da				
Notice of Draitsperson's Patent Drawing Review (FTO-946)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)     Paper No(s)/Mail Date <u>5/9/05</u> .		atent Application (PTO-152)			

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#### **DETAILED ACTION**

# Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 7, 8, 11, 12, 15, 18, and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-10 of U.S. Patent No. 6,676,659. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim a method of cutting tissue in a body passage and a catheter handle, where the method includes, inter alia, selecting a catheter having first and second lumens, actuating an electrosurgical wire in the second lumen, orientating and rotating the electrosurgical cutting wire by rotating a handle relative to a proximal end of the catheter, and indicating an amount of rotation via a visual indication; and where the catheter handle includes a rotatable coupling

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configured to allow free rotation of a proximal end of a catheter, a clamping member configured to engage a proximal end of a device extending through a lumen of a catheter, where the device includes a cutting wire, and where the handle includes a rotation indicator that is a visual indicator.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not certain whether the catheter handle includes a catheter and a device comprising a cutting wire extending from a proximal end of the catheter to and connecting to a distal end of the catheter.

#### Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 7, 8, 10-12, and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver et al. (5,599,300). Weaver et al. disclose, in figures 4 and 34-36 and in col. 19, lines 11-66, a catheter handle and a method for its use in a method for cutting tissue in a body passage, where the handle (202) and the method include a

catheter (12) with proximal and distal ends and first and second lumens (32, 34) and an electrosurgical cutting wire (206), where the handle (202) engages and rotates the proximal end of the cutting wire (about its axis during assembly) or a device and has a

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clamping member (224), a rotatable coupling (14, see also col. 19, lines16-20) attaching

the handle to the catheter, a rotation lock (17, a threaded luer lock hub according to col.

19, lines 52-60), and a rotation indicator or a visual indicator of handle rotation (distal

surface portion of 17).

## Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Agro et al. (6,746,442) teach a catheter handle, catheter, and a device with a cutting wire.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo Primary Examiner

Julian W. Moo

July 21, 2006